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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,397	10/16/2001	Daniel Schubart	AXM-004.1 US	6812

7590 07/21/2003

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/981,397	Schubart et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 9, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) *2-19 and 22-28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 20, and 21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Oct 16, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I (claims 1, 20, 21 within the scope of SEQ ID NO: 16) in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the embodiments of the invention share common features, and fractionation of the claims would lead to repetitive examination and undue expense. In addition, applicants argue that no undue search would be required because the groups are classified in one class i.e. 435. Applicants further argue the claims of Groups I-III, V and VI would reveal the same art. This is not found persuasive because, applicants provide no evidence that indicates the search would reveal the same art. Group I is directed to identifying agents, Group II is directed to detection of cytomegalovirus, etc..., detecting cytomegalovirus infection and agents are vastly different one from the other. In addition, classification of subject matter is merely one indication of the burdensome nature of the search involved. Still further, the subclass within the classified group are vast. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden search. The various kinases have different structures they are distinct one from the other. Applicants do not present argument to the contrary. Clearly different searches and issues are involved in the examination of each group. As for the assertion regarding undue expense, applicants are reminded that the expense is a business decision and has no bearing on the burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-19, 22-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, Applicant timely traversed the restriction (election) requirement in Paper No. 15. Applicants are reminded that the elected claims 1, 20, and 21 have been examined only within the elected SEQ ID NO: 16, RIP kinase

Applicants are reminded to cancel the claims to the non elected claims.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Please note the claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and do not conform with current U.S. practice. The correction is respectfully requested.

Claim Rejections - 35 USC § 112

Claims 1, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "associated diseases", what are the associated diseases? Is migraine an intended associated disease? In addition, the claim is vague and indefinite for recitation of "change in activity" this is a relative terminology, what applicants deem to be a change might not be a change. How is the "change" determined, visually, or chemically? Moreover, is the increase in activity or decrease in activity of the kinases that determines a compound as a viable candidate for treating or preventing cytomegalovirus infection? How much change is to be deemed as a base for determining whether or not a compound is useful? Still further, the claim is very confusing, because the method does not set forth any step(s) for how the measuring is/are determined, and sufficient steps that would allow the practice of the claimed invention. There are so many variables present that one of skill in the art would not know what to add, when to add, what to measure, and when to measure? Shouldn't there be a control of some sort present? Is the kinase within the cell or is the kinase sequence by itself being utilized? Is the compound measuring changes in infected cells or non-infected cells? Is the compound as such that binds to the kinase or inhibits it expression or what is the compound suppose to do? How does change of activity relate to treating or preventing

cytomegalovirus? Are the kinase gene the intended targets or its protein? Are the kinases down regulated by the cytomegalovirus or up regulated? Please clarify?

Claims 20, and 21 are vague and indefinite the intended oligonucleotide or kinases should be identified by a specific sequence identification number. In addition, the claims are vague and indefinite since no conditions are present which would allow the appropriate screening to take place. How can one know whether or not a compound is useful when no direction is given? Is the compound suppose to kill cells or bind the kinase or inhibit its expression?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhu et al (PNAS USA, 1998, Vol. 95, pp. 14470-14475).

The claims are directed to utilizing cellular expression of kinase Rip in determining compounds that maybe useful in treating cytomegalovirus. Zhu et al already provided ample teaching in the above cited article about the method and assay of utilizing Rip kinase in

determination of cytomegalovirus infection. Zhu et al taught that when cells are infected with cytomegalovirus certain genes such as Rip kinase is up regulated and detection of such activity would lend itself in detecting compounds that would be useful in treating cytomegalovirus infection (see the entire document, especially the abstract, and Table 1, page 14472, bottom of left column).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 20, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gingeras et al (WO 00/011218 A1).

The above cited reference anticipates the now claimed invention. Gingeras et al taught the method and assay of utilizing Rip kinase in determination of cytomegalovirus infection and screening for compounds (see the abstract, see pages 38-42, and all claims especially claim 3).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Baichwall et al (US Patent No. 6,211,337 B1).

The claims and teaching of the above cited art anticipates the now claimed invention. The method and assay disclosed in above cited patent clearly anticipates the now claimed invention. Applicants' invention is directed in looking at and are targeting "activity" of RIP kinase. The above cited patent also directed a method that measured interaction of RIP. Baichwall et al taught

and claimed utilization of Rip kinase in screening for an agent which would target RIP kinase (see claim 3, and column 4, lines 8-27). Applicants are reminded that the in-house sequence search has reveled SEQ ID NO: 2 as disclosed by Baichwall et al being 100% identical to the SEQ ID NO: 16 that is being utilized in the method and assay of now claimed invention.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

7/18/2003

ALI R. SALIMI
PRIMARY EXAMINER